DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/29/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The rejection of claims 32-41, 43, 46 and 49-52 under 35 U.S.C. 103(a) as being unpatentable over Dioguardi (U.S. Patent No. 6,218,420) is withdrawn in view of the arguments and declaration under 37 CFR 1.132 filed 03/29/2010.

3. The rejection of claims 43, 46 and 49-52 under 35 U.S.C. 103(a) as being unpatentable over Conti et al. (U.S. 20040157903) is withdrawn in view of the arguments and declaration under 37 CFR 1.132 filed 03/29/2010.

Double Patenting

4. The provisional rejection of claims 43, 46 and 49-52 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-35 of copending application 12/104,722 is withdrawn in view of the terminal disclaimer filed 03/29/2010.

Examiners Amendment

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Andrew Gonsalves on March 8, 2011.

The application has been amended as follows:

In claim 32, line 5, insert the word –the—prior to "branched chain amino acids" and insert the word –and—prior to "valine".

Reasons for Allowance

6. The following is an examiner's statement of reasons for allowance: the instant claims are drawn to methods of administering amino acid compositions wherein the compositions have specific ratios of the constituent amino acids.

7. The compositions require:

(i) the branched amino acids leucine, isoleucine and valine,

(ii) lysine and threonine, and

(iii) the other essential amino acids histidine, methionine, phenylalanine and tryptophan,

wherein the amount in moles of threonine is less than the individual amounts of lysine, leucine, isoleucine and valine but greater than the sum of the individual amounts in moles of the other essential amino acids, and

wherein the amount in moles of lysine is less than the individual amounts of leucine, isoleucine and valine but greater than the sum of the individual amounts in moles of the other essential amino acids.

8. Although methods of administering compositions comprising these amino acids are known in the art, the prior art does not teach compositions with this specific ratios. A comparison of the three closest prior art documents with the instant claims is as follows:

	MW	Dudrick et al (US 5,026,721)		Schmidl et al. (US 5,719,133)		Troup et al. (US 2004/0087490)	
		g	moles	g	moles	g	moles
leucine	131.1736	9.3	0.071	8	0.061	3.2	0.024
isoleucine	131.1736	5.3	0.040	5.8	0.044	1.9	0.014
valine	117.1469	6.5	0.055	6.6	0.056	2.2	0.019
lysine	146.1882	13.4	0.092	8.8	0.060	3.9	0.027
threonine	119.1197	3.7	0.031	4.5	0.038	1.9	0.016
histidine	155.1552	2.7	0.017	2.9	0.019	2	0.013
methionine	149.2124	2.9	0.019	2.9	0.019	1	0.007
phenylalanine	165.19	2	0.012	5.2	0.031	1.6	0.010
tryptophan	204.2262	1.2	0.006	1.6	0.008	0.5	0.002
sum of other essential			0.055		0.077		0.032
difference with the instant claims		threonine < sum of other essential amino acids		threonine < sum of other essential amino acids; lysine < sum of other essential amino acids		threonine < sum of other essential amino acids; lysine < sum of other essential amino acids	

9. Neither Dudrick et al., Schmidl et al. or Troup et al. teach or suggest formulation that meet the ratio requirements of the instant claims. Furthermore, neither Dudrick et al., Schmidl et al. or Troup et al. teach that the compositions are for maintaining intact, restoring and/or increasing the number of cellular mitochondria in elderly subjects or for treating apoptosis of mitochondrial origin. Therefore, there is no reasonable expectation that routine optimization of the amounts of amino acids in the compositions would result in the instantly claimed ratios. Therefore, the claims are novel and unobvious over Dudrick et al., Schmidl et al. and Troup et al.

Conclusion

10. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA BRADLEY whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 8:30 A.M. to 4:30 P.M.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina Marchetti Bradley/
Primary Examiner, Art Unit 1654

cmb